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10/587,817

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EXAMINER

KESSEL, MARIS

ART UNIT

PAPER NUMBER

4142

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/587,817

Applicant(s)

CHEN ET AL.

Examiner

MARIS R. KESSEL

Art Unit

4142

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 August 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>08/02/2006</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Drawings

1. Figure 1 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 5 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 5 recites the limitation "the cell adhesive region" in the first line. There is insufficient antecedent basis for this limitation in the claim. It is likely that claim 5 is dependent on claim 4. To remedy this defect, Examiner is treating this claim as dependent on claim 4. Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-8 and 10-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Vogel et al. (Pub. No. US 2003/0098248) (hereinafter “Vogel”).

Regarding claim 1, Vogel discloses an apparatus for arraying particles (example 5, multiaperture system shown in figs. 6 and 7), the apparatus comprising:

a substrate (192) comprising an array of electrodes (196a) (figs. 6 and 7, examples 2 and 5, para. [0078]);

a counter-electrode plate substantially parallel to the array of electrodes ((196b) on plate (206), single planar plate electrode disclosed in fig. 3, electrode (76b));

a fluid inlet for permitting a particle-containing fluid to flow between the array of electrodes and the counter-electrode plate (para. [0109] describes positioning, [0098] describes sample handling system; flow of a sample to the aperture is necessary and inherent to the functioning of the devices, and such flow takes place between the electrode array and the electrode plate).

Regarding claim 2, Vogel discloses a voltage source for applying a voltage between the array of electrodes and the counter-electrode (electric potential between electrodes (76a) and (76b) or (196a) and (196b), paras. [0075]-[0080]).

Regarding claim 3, Vogel discloses wherein the voltage source provides a voltage no greater than about 100 volts/mm (field of 0.1 V/mm or greater disclosed in para. [0079]).

Regarding claim 4, Vogel discloses the apparatus having at least one cell-adhesive region (para. [0060]) and at least one non-cell-adhesive region (fig. 7, regions with hydrophobic coat (204) described in para. [0144]).

Regarding claim 5, Vogel discloses wherein the cell adhesive region comprises a layer of fibronectin or collagen (para. [0063]).

Regarding claim 6, Vogel discloses a fluid outlet (a sample handling system for adding and removing samples from the device, para. [0098]).

Regarding claim 7, Vogel discloses wherein the electrode array comprises at least 50 electrodes (table within para. [0085]; each site requires one electrode in the array, para. [0155]).

Regarding claim 8, Vogel discloses wherein the electrode array comprises at least 100 electrodes (table within para. [0085]; each site requires one electrode in the array, para. [0155]).

Regarding claim 10, Vogel discloses independently energizing each electrode of the array (para. [0145]).

Regarding claim 11, Vogel discloses using the apparatus described above in claim 1 in a method comprising the steps: flowing a particle-containing fluid between the array of electrodes and the counter-electrode plate (paras. [0109] and [0132]); and subjecting the fluid to an electric field by applying an electric potential to the array of electrodes under conditions such that particles in the fluid are arrayed on a surface of a substrate (para. [0109]).

Regarding claim 12, Vogel discloses wherein the particles are cells (para. [0103]).

Regarding claim 13, Vogel discloses the apparatus having at least one cell-adhesive region (para. [0060]) and at least one non-cell-adhesive region (fig. 7, regions with hydrophobic coat (204) described in para. [0144]).

Regarding claim 14, Vogel discloses wherein the cell adhesive region comprises a layer of fibronectin or collagen (para. [0063]).

7. Claims 1, 2, 4-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Talary et al. (Pub. No. US 2004/0226819) (hereinafter "Talary").

Regarding claim 1, Talary discloses an apparatus for arraying particles (para. [0007]) comprising:

- a substrate (200) comprising an array of electrodes (411-415) (para. [0070]);
- a counter-electrode plate (420, fig. 4a) substantially parallel to the array of electrodes;

- and a fluid inlet (210) for permitting a particle-containing fluid to flow between the array of electrodes and the counter-electrode (para. [0053]).

Regarding claim 2, Talary discloses a voltage source for applying a voltage between the array of electrodes and the counter-electrode (electric potential between electrodes, para. [0070]).

Regarding claim 4, Talary discloses the apparatus having at least one cell-adhesive region and at least one non-cell-adhesive region (para. [0079]).

Regarding claim 5, Talary discloses wherein the cell adhesive region comprises a layer of fibronectin or collagen (para. [0079]).

Regarding claim 6, Talary discloses a fluid outlet (220) (para. [0053]).

Regarding claim 7, Talary discloses wherein the electrode array comprises at least 50 electrodes (para. [0072]).

Regarding claim 8, Talary discloses wherein the electrode array comprises at least 100 electrodes (para. [0072]).

Regarding claim 9, Talary discloses wherein each electrode of the electrode array is less than 100 microns in diameter (para. [0071]).

Regarding claim 10, Talary discloses independently addressing each electrode of the array (positive or negative non-uniform forces can be applied; para. [0024]).

Regarding claim 11, Talary discloses using the apparatus described above in claim 1 in a method comprising the steps: flowing a particle-containing fluid between the array of electrodes and the counter-electrode plate (para. [0056]); and subjecting the fluid to an electric field by applying an electric potential to the array of electrodes under conditions such that particles in the fluid are arrayed on a surface of a substrate (para. [0056]).

Regarding claim 12, Talary discloses wherein the particles are cells (para. [0048]).

Regarding claim 13, Talary discloses the apparatus having at least one cell-adhesive region and at least one non-cell-adhesive region (para. [0079]).

Regarding claim 14, Talary discloses wherein the cell adhesive region comprises a layer of fibronectin or collagen (para. [0079]).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vogel as applied to claim 1 above.

Regarding claim 9, Vogel discloses electrodes with diameters as low as 100 microns (para. [0135]).

Vogel fails to disclose electrodes with diameters less than 100 microns.

However, Vogel discloses and suggests the miniaturization of components of their system, in order to accommodate more measurement sites within a given area (see paras. [0085], [0256], and [0304]), and scaling of the system to 9600 measurement sites or more as suggested in para. [0085] would require appropriate scaling of features such as electrodes and the lead wires connecting them.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teaching of Vogel before him or her, to modify the size of the electrodes by such scaling to less than 100 microns.

The suggestion for doing so would have been to accommodate more measurement sites within a given area (paras. [0085], [0256], and [0304]).

11. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Talary as applied to claims 1 and 2 above and further in view of Vogel.

Regarding claim 3, Talary is silent as to the applied voltage amount.

However, Vogel discloses an apparatus for arraying particles (example 5, multiaperture system shown in figs. 6 and 7), wherein the voltage source provides a voltage no greater than about 100 volts/mm (field of 0.1 V/mm or greater disclosed in para. [0079]).

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Talary and Vogel before him or her, to modify the

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electric field as taught by Talary to apply a voltage less than 100 volts/mm as taught by Vogel.

It would have been well within the skill of one having ordinary skill in the art at the time the invention was made to select an appropriate voltage for use in manipulating particles. Additionally, a skilled artisan would have recognized that the range of useful field strengths would include those below 100 V/mm.

The motivation for doing so would have been to enable independent measurement sites for positioning and analyzing samples (Vogel, paras. [0145] and [0150]).

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Miles (Pub. No. US 2002/0088712) (hereinafter "Miles") discloses an apparatus for arraying particles (fig. 4, abstract, para. [0004]) comprising: a substrate comprising an array of electrodes (12-20) (para. [0020], electrodes are disposed on a substrate that defines a channel wall); a counter-electrode plate (23) substantially parallel to the array of electrodes; and a fluid inlet for permitting a particle-containing fluid to flow between the array of electrodes and the counter-electrode (fig. 6, sample inlet (56); para. [0025]). Albritton et al. (WO 2003/093791 A2) (Equivalent found at Pub. No. US 2004/0058423) discloses a cell arraying device wherein adhesion of the cells to a desired region is aided by the provision of a cell adhesion layer, which can comprise collagen or fibronectin (paras. [0053] and [0060]).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARIS R. KESSEL whose telephone number is (571)270-7698. The examiner can normally be reached on Monday through Friday, 8 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alexa Neckel can be reached on (571)272-1446. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M.K./

M.K.

Examiner, Art Unit 4142

/Alexa D. Neckel/

Supervisory Patent Examiner, Art Unit 1723